

## PATENT COOPERATION TREATY

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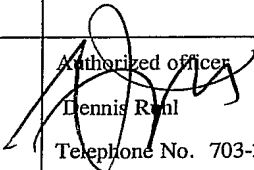
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference END-861	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/16695	International filing date (day/month/year) 28 May 2002 (28.05.2002)	Priority date (day/month/year) 29 May 2001 (29.05.2001)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61H 1/00 and US Cl.: 601/2		
Applicant ETHICON ENDO-SURGERY, INC.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 13 NOVEMBER 2002 (13.11.02)		Date of completion of this report
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer  Dennis Ruhl Telephone No. 703-308-2262

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US02/16695

**I. Basis of the report**1. With regard to the **elements** of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-44 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 45-48, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-15, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US02/16695

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>2, 3, 5, 6, 8, and 9</u>	YES
	Claims <u>1, 4, 7, and 10-13</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-13</u>	NO
Industrial Applicability (IA)	Claims <u>1-13</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Claims 1, 4, 7, 10-13 lack novelty under PCT Article 33(2) as being anticipated by HENNIGE et al (US 5,492,126).

Claims 1, 4, and 7: Hennige discloses of all claimed inventions in claims 1, 4, and 7. Hennige's ultrasound probe consists of an end effector having an ultrasound medical treatment transducer assembly (col. 3, lines 46-53) where the transducer is designed to focus ultrasound energy to a desired focal zone of the tissue to achieve temperature increase in tissue to provide effective ultrasound therapy (col. 4, lines 31-41). Hennige also discloses of correcting the desire focal zone from the actual focal zone via feedback (col. 4, lines 31-41). In addition, Hennige anticipates that the invention may include imaging transducer configures to image the tissue under therapeutic procedure (col. 4, lines 42-51).

Claims 10 and 11: Hennige further discloses of ultrasound therapy device in which the inventions described above are applies directly to endoscopy to laparoscopy (col. 3, lines 34-44).

Claims 12 and 13: Hennige also discloses of probe or catheter with ultrasound therapy (col. 3, lines 46-67) where the tip of the catheter or the probe may be a needle (col. 4, lines 17-31).

Claims 2, 3, 5, 6, 8, and 9 lack an inventive step under PCT Article 33(3) as being obvious over HENNIGE et al in view of BURDETTE et al (US 5,391,197).

Hennige substantially discloses of all claimed inventions in claims 2, 3, 5, 6, 8, and 9 where the ultrasound therapy is used to raise the temperature of patient's tissue. Burdette discloses of ultrasound catheter for ultrasound therapy includes feedback for temperature control where the ultrasound application is halted once the desired temperature has been exceeded. The level of threshold as claimed in the application is a design choice where Burdette clearly anticipates. Hennige's system does not specifically discloses of temperature threshold, however, the operating temperature is stated. To control the operating temperature range or more specifically, desired temperature, Burdette's temperature control demonstrates the mechanism and applicability. Therefore, it would have been obvious to combine the inventive steps of Hennige and Burdette to achieve the claimed inventions.

#### ----- NEW CITATIONS -----

US 5,492,126 A (HENNIGE et al) 20 Feb. 1996, see column 3, lines 34-67; column 4, lines 17-51;  
US 5,391,197 A (BURDETTE et al) 21 Feb. 1995, see entire document.